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Comm. Amdt. _____
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AMENDMENT NO._____

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Signature of Sponsor

AMEND Senate Bill No. 354* House Bill No. 816

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding Sections 2-5 as new sections to be appropriately designated.

SECTION 2. No formulary, prior authorization process or treatment protocol shall be used by a Managed Care Organization ("MCO") in making coverage and payment decisions concerning practitioners' lawful use of prescription drugs in treating TennCare enrollees unless it meets the requirements of this Act.

SECTION 3.

(a) Any drug covered by TennCare but prior authorized or otherwise restricted by an MCO or its subcontractor must be paid for by the MCO when the drug is medically necessary for a specific enrollee.

(1) In reviewing the medical necessity of a new prescription, due deference shall be given to the clinical judgment of the patient's treating physician unless the standard drug compendia or peer-reviewed literature provides clear and convincing evidence that the prescribed drug does not provide a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome for treating the patient's condition.

(2) Renewal or refill of a prescription that the treating physician considers a "maintenance medication" shall be considered medically necessary.

(3) Each MCO shall comply with the TennCare Bureau's expedited authorization and appeals process for reviewing payment denials.

(b) Each new chemical entity and each new dosage form of an existing chemical entity that is marketed under a Product Licensing Application or a New Drug Application (or supplement thereto), shall be available without prior authorization for a reasonable period of time after it is first marketed to provide the MCO and its participating physicians sufficient clinical experience to determine whether the drug provides a meaningful therapeutic advantage for treating enrollees.

SECTION 4.

(a) The MCO or its subcontractor's authorization procedures shall be capable of providing a response in less than twenty-four (24) hours and shall provide that:

(1) a request for authorization of a non-preferred drug submitted before noon is deemed approved if an answer is not received for product dispensing on the same business day as the request;

(2) a request submitted before 9:00 PM is deemed approved if an answer is not received for product dispensing before noon of the next calendar day; and

(3) in the event of a negative response, the enrollee may indicate to the pharmacy or other practitioner that the enrollee wishes to appeal, and any drug that the prescriber has indicated is for an "urgent" condition will promptly be

dispensed to the enrollee as prescribed and paid for by the MCO pending outcome of such appeal.

(b) Any prior authorization requirement that applies differentially to prescription drugs within the same therapeutic class that are not pharmaceutically equivalent and bioequivalent must meet the formulary requirements.

SECTION 5. Any formulary or other device used by the MCO or its subcontractors to exclude or restrict payment for an FDA-approved drug or biological product lawfully used by a practitioner in treating a TennCare enrollee must satisfy the following requirements:

(a) Any formulary must be developed and periodically updated by a panel of physicians practicing in the state or region, including primary care practitioners that participate in the MCO, as well as specialty physicians, pharmacists, and others with expertise in the use of outpatient prescription drugs as part of a comprehensive program of patient care.

(1) No member of a formulary committee may be a government employee, and any formulary committee organized or supervised by any entity other than the MCO must be composed of individuals who have no business-related conflicts of interest.

(2) The names, addresses and professional qualifications of the MCO's current committee members shall be on file with the Bureau of TennCare, which

may recommend changes in composition to ensure compliance with this subsection.

(b) Any exclusion of a particular product or prerequisites on coverage and payment for a particular pharmaceutical or biological entity lawfully prescribed by a practitioner must meet the following clinical standards:

(1) The formulary committee may restrict or exclude coverage of a specific prescription drug only if there is a written finding of the committee (available to the public) that, based on the drug's labeling or the peer reviewed medical literature the drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome for treatment of a particular indication in the enrollee population.

(2) The MCO shall establish a process for reconsidering the formulary status of any drug upon the request of any participating physician, provider or a specialist from a relevant medical specialty, based on clinical or scientific evidence concerning a drug’s safety, effectiveness, or clinical outcome.

SECTION 6.

(a) Each MCO that uses a formulary or other drug list shall promptly file a copy of any such list and revisions thereof with the bureau of TennCare; shall furnish a current copy and revisions thereof to each participating provider, and upon payment of the cost

of duplication, shall furnish copies to any interested person within thirty (30) days of a request.

(b) Each MCO that uses a formulary or other device to restrict coverage and payment for drugs shall make arrangements to promptly answer an enrollee or prospective enrollee's questions concerning coverage and payment for a particular prescription drug product.

(c) In addition to any remedies available to individuals, the Bureau of TennCare shall establish a process for examining and verifying MCOs' compliance with the requirements of this act, including but not limited to:

(1) ensuring that prior authorization systems meet performance specifications;

(2) resolving complaints or questions raised by providers, beneficiaries or other interested persons concerning availability of a given product in a particular MCO; and

(3) taking such actions as may be necessary to ensure that an MCO brings its formulary into compliance with this act, including but not limited to enjoining use of a formulary, limiting new enrollment, and/or barring an MCO (or a subcontractor) from renewing or entering into new contracts to serve TennCare beneficiaries.

SECTION 7. This act shall take effect on July 1, 1997, the public welfare requiring it.